

Appl. No. : 10/035,822
Filed : December 27, 2001

REMARKS

The Specification has been amended to correct the trademarks and to include generic terminology of the trademarks. Claims 52, 60, 63, 71, and 72 have been amended. New Claim 87 has been added. Support for the Claim amendments can be found in the Specification as filed, for example, on page 11, lines 18-25. The generic terminology of the trademarks is freely available from the producers of the compounds and therefore does not constitute new matter. The following addresses the substance of the Office Action.

Specification

The Examiner requested capitalizing the trademarks which appear in the Specification and adding a generic terminology to the trademarks: TWEEN, TRITON X100 and NP40. The Applicant has now corrected the appearance of the names of trademarked compounds and included their generic terms.

Sequence Listing

Please amend the application to include the Sequence Listing provided herewith in response to the Notice to Comply which accompanied the Office Action.

Requirement for Information

The Examiner has requested specific information pertaining to the first offer for sale and use of "Hepatochips" and "Bio-CD reader", and how these products are encompassed, or not encompassed by the currently pending claims.

The Applicant responds as follows: the term "Bio-CD reader" corresponds to a normal CD reader, which further comprises a second reading head for the analysis of the biological information (for the detection and/or the quantification of a signal (such as, for example, a silver deposit) resulting from the binding of a target molecule upon its complementary capture molecule), see for example pages 58-59 of the Specification. "Bio-CD" is discussed on the Applicants web site (see appendix 1). However, the products "Bio-CD" and "Bio-CD reader" are not yet sold in the USA. The sale of "Hepatochips™" microarrays is irrelevant to the present invention, as these are low-density microarrays on glass slides (see Appendix 2, page 14), and are not discs.

The main differences between the present CIP application and US 09/582,817 are as follows:

- fixation of capture molecules upon the CD surface according to an array,

- fixation of capture molecules upon the CD surface area(s) opposite to the surface area(s) comprising the registered data,
- expanded discussion on embodiments having chambers, cavities and microchannels upon the CD surface ,
- description of a CD platform,
- expanded discussion on the term " registered data", and
- more examples of capture and target molecules bound upon a CD. More specifically, the Examples 4, 5, 7-16 and Figures 7-20 are new compared to the parent application.

Applicants are not aware of any publications authored by the inventors which describe the claimed invention which have not been provided to the Examiner.

Written Description

Claims 45-86 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More specifically, the Examiner indicated that the Specification does not provide specific written description of immobilized nucleic acids, nor how they are immobilized.

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991). In view of the recent decision by the Federal Circuit, *Union Oil of California*, it is clear that an Applicant need not precisely recite each and every element of a claim limitation in the specification in order to satisfy the written description requirement. *See Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000).

In the present application any skilled artisan can easily recognize that any desired nucleic acid can be bound to the disc using the methodology provided in the specification. The chemical properties common to all nucleic acids can be utilized to bind them to the disc. Applicants have provided some exemplary sequences which could be bound to the disc in the specification and have provided the meaning of the term nucleic acid, oligonucleotide etc. on page 7, lines 13-17. However, it is not necessary for Applicants to recite all the specific sequences which can be

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bound to the disc. Just as those skilled in the art can appreciate that any desired nucleic acid could be used as a probe on a nitrocellulose filter, those skilled in the art would similarly appreciate that any desired nucleic acid could be bound to the surface of the disc.

The Examiner has rejected Claim 67 because the Specification does not provide a written description of "words, numbers, music, software and data bases" as digital information. The Applicant asserts that one skilled in the art would know how to convert an output data (digital information, as electronic string of 1's and 0's) into any desired form be it words, numbers, notes, etc. Thus, Applicants need not provide the specific words, database layout, numbers etc. which are provided by the digital information.

The Examiner has rejected Claims 73 and 86 for defining the reactants in the kit by their function, and not by what they are. The Applicant asserts that the specific components needed for binding between the target molecule in a sample and a capture molecule attached to the disk, and/or the specific compounds needed for the detection of the resulting reaction depend on the particular type of said binding (page 21, lines 19-page 22, line 8) and on the specific type of signal obtained once the binding occurred (page 23, line 25 - page 24, line 26, line 3). These specific components are well-known in the art, and therefore specific recitation of their ingredients is not necessary. Therefore, the Applicant respectfully requests withdrawal of the rejection of Claims 73 and 86.

The Examiner has rejected Claim 72 for lack of description of the term "protective layer". The Applicant has amended claim 72 to include such a description, as supported in the Specification as filed, on page 11, lines 18-25. Therefore, the amended Claim 72 and the new Claim 87 are enabled.

The Examiner has rejected Claims 74-80 for lack of a written description of the term "detection and/or reading device". The Applicant respectfully disagrees. The specification and Figures provide a description of the detection and/or reading device. For example, page 15, lines 8-27, page 22, line 9-page 23, line 5, page 37, line 10-page 42, line 6 and Figures 1, 3-6, and 11-14 describe the devices used to detect and read the discs. Applicants further point out that those skilled in the art are familiar with the use of lasers to read data from a disc (such as a CD or DVD) and that the guidance in the specification in combination with the knowledge of those skilled in the art is sufficient to allow one skilled in the art to appreciate that Applicants were in possession of the claimed device.

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The Examiner has rejected Claims 80-85 for lacking written description of the terms "handling device" and "apparatus". The handling device is described in the specification at page 37, lines 10-30, Figure 10. Applicants maintain that the guidance in the specification in combination with the knowledge of those skilled in the art is sufficient to allow one skilled in the art to appreciate that Applicants were in possession of the claimed device.

The Examiner has rejected Claims 45-86 for lacking the specific description of how the disk, reader, handling device or apparatus can be used in quantitative determination of any nucleic acid. Applicant respectfully disagrees. Claims 74-80 specifically describe a reading head for the detection and/or quantification of the signal which results from the binding between target molecule and its capture molecule. Such binding is described in the Specification as filed (page 23, line 25 - page 24, line 26, line 3). The Specification also provides specific examples of detecting a DNA on a CD (Example 1, page 47 line 12 through page 49, line 18). Once a signal is recorded (for example, as a digital data), it can be compared to another such signal, hence quantified. Such procedure is fundamental to any scientific research, and therefore is within the abilities of a skilled artisan. Applicant therefore respectfully asserts that the specifics of how a nucleic acid is quantified are not necessary in the Claims.

Therefore, Claims 45-86 are supported by the Specification as filed, and their rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

Enablement

The Examiner has rejected Claims 45-86 under 35 U.S.C. §112, first paragraph for failing to comply with enablement requirement. More specifically, the Examiner stated that the specification does not provide an adequate written description of the nucleic acids that are immobilized on the surface of a disc. Applicant respectfully disagrees.

In *Regents of University of California v. Eli Lilly & Co.*, the Federal Circuit held that enablement of a genus under § 112, ¶ 1 may be accomplished by showing the enablement of a representative number of species within that genus. 119 F.3d 1559 (Fed. Cir. 1997). Enablement "is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive." See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986). "To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation' ... Nothing more than objective enablement is required, and

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therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *See In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993).

In this application Tables 2 and 3 provide a list of specific nucleic acid sequences that can be immobilized on the surface of a disc. As discussed above, ALL nucleic acids share common chemical properties allowing them to be bound to the surface of a disc. Moreover, the Specification provides examples of detecting of a specific DNA hybridized to target molecules on the disc (Examples 1 and 7). Therefore, Applicant respectfully asserts that the Claims 45-86 are enabled and their rejection should be withdrawn.

Indefiniteness

The Examiner has rejected Claims 47, 48, 52, 60, 63-64, and 71 under 35 U.S.C. §112, second paragraph as being indefinite. More specifically, Claims 47 and 48 were rejected for lack of antecedent support for the term "the registered data"; Claim 52 was rejected for lack of antecedent support for "the location of the samples"; Claim 60 was rejected for reciting "some" which lack metes and bounds; Claims 63 and 64 were rejected for lack of antecedent support for "said portion"; and Claim 71 was rejected for "extremity of the capture molecule" which is a confusing term with respect to a nucleic acid. Applicant wishes to point out that Claim 45, to which claims 47 and 48 depend, recites; "A disc comprising registered data", therefore "the registered data" in Claims 47 and 48 have antecedent basis. Applicant has amended Claim 52 to now recite "location of the samples", Claim 60 to now recite "a specific location"; Claim 63 is now dependent on Claim 61, therefore Claims 63 and 64 now have antecedent basis for reciting "said portion"; and Claim 71 has been amended to recite "one end", as a non-circular nucleic acid molecule is known to have two ends. Therefore, Claims 47, 48, 52, 60, 63-64, and 71 are now definite and their rejection should be withdrawn.

Double Patenting

The Patent Office rejected claims 45-69 on the grounds of obviousness-type double patenting over claims 49 and 50 of copending Application No. 09/582,817. A terminal disclaimer may be used to overcome an obviousness-type double patenting rejection. Applicant will defer filing a terminal disclaimer until the rejected claims are otherwise indicated to be in condition for allowance.

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CONCLUSION


Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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